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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/406,473	09/27/1999	STEPHEN D. PACETTI	M-7395US	1646

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CAMERON KERRIGAN
SQUIRE, SANDERS & DEMPSEY LLP
ONE MARTINE PLAZA
SUITE 300
SAN FRANCISCO, CA 94111-3492

EXAMINER

THANH, LOAN H

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 05/20/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

Office Action Summary	Application No.	Applicant(s)	
	09/406,473	PACETTI, STEPHEN D.	
	Examiner	Art Unit	
	LoAn H. Thanh	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8, 58, 59, 64, 65, 69 and 70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8, 58-59, 64-65, 69-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 56, 64 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al. (U.S. Patent No. 5,674,192).

Sahatjian et al. disclose a medical kit comprising a coated stent deployed by a balloon catheter wherein the stent is coated with a therapeutic substance. Further, it is disclosed that the sheath is made of polyurethane or TEFLON (fluorinated polymer). Sahatjian et al. teach the sheath is for protecting the drug/coating and for inhibiting premature release of the drug. The protective sheath is for preventing the release of the drug prior to reaching the desired location in the body. See col. 1-3, 8, 10-11, 14. The Examiner is taking the position that it is inherent that the polyurethane has a glass transition temperature (T_g) that is above storage temperature. In the broadest interpretation the storage temperature has not been specified, thus the temperature can be any temperature. Further, it would be inherent for the T_g to be above storage temperature since the sheath would be a solid structure. If the T_g was below the storage temperature then the sheath would be a liquid or unstable form during storage.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-8,57-58,65,70 are rejected under 35 U.S.C. 103(a) as obvious over Sahatjian et al. (U.S. Patent No. 5,674,192).

Sahatjian et al. disclose the invention substantially as claimed. However, Sahatjian et al. does not disclose the non-polar soft segment to be hydrocarbons or silicones or fluorosilicons or mixtures thereof. It is common knowledge in the chemical art to modify the non-polar segments in order to provide properties such as flexibility and bendability which are desired in the medical arts. In absence of convincing objective evidence to the contrary, it would have been obvious to modify any medically acceptable material to the essential properties, which are desired.

With respect to claims 8,58, 65,70 it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the layer of the sheath to provide desired properties such as flexibility, bendability, biodegradability, water solubility and chemical inertness of the polymer by chemically enhancing the properties of the polymer layer as common knowledge in the chemical art. In absence of convincing objective evidence to the contrary, it would have been obvious to modify any medically acceptable material to the essential properties, which are desired.

Art Unit: 3763

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Further, applicant's specification has disclosed suitable combinations of barrier polymers and therapeutic substances but has also disclosed that other suitable combinations are possible. Applicant has also disclosed that in the broader aspects of the invention the sheath may not be in contact with the therapeutic agent and thus the therapeutic substance would not absorb or diffuse into the sheath material.

Applicant is suggested to show or provide criticality or unexpected results of the claimed properties of these materials.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday to alternating Fridays (7:00 am-4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Art Unit: 3763

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read 'LoAn H. Thanh', with a stylized flourish at the end.

LoAn H. Thanh
Examiner
Art Unit 3763

LT